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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,200	05/29/2001	Shujath M. Ali	DEX-0192	2228

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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,200	ALI ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *2-5 and 7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group I, claims 1, 6, SEQ ID NO:1, species tissues in Paper No. 9 is acknowledged. The traversal is on the ground(s) that 1) the Examiner statement that groups I-IX lack the same or corresponding special technical feature contradicts the Search report and the Written Opinion issued in the PCT application of which this case is the US national stage, because clearly the CSG polypeptide is a single general inventive concept linking all the groups of a method for detecting a polynucleotide or a polypeptide encoded thereby, and antibodies against that polypeptide, 2) it woud not be a serious burden for the Examiner if the restriction is not required, because the prior art relating to all the claims has already been performed in the PCT application, and 3) Concerning species requirement, any search using a specified CSG would reveal references teaching diagnostic methods in cells, tissues and bodily fluid. This is not found persuasive because clearly groups I-IX are not so linked as to form a single general inventive concept under PCT rule 13.1, for the reasons already of record in previous Office action. That is Groups III, V are additional use claimed for SEQ ID NO:1. Groups II, IV, VI, VIII-IX are additional methods, which do not share the same technical feature of group I, because they use reagents, such as the CSG polypeptide of SEQ ID NO:2, or an antibody specific for the CSG polypeptide of SEQ ID NO:2, that do not share a common structure as the polynucleotide of SEQ ID NO:1 of group I and are not recited in the method of group I. Further, Group VII is drawn to a composition, which does not share the same technical feature of group I, because the antibody of group VII does not share a common structure as the polynucleotide of

SEQ ID NO:1. Thus, because the different groups do not share a common technical feature for the reasons set forth above, and because the searches for these groups are not co-extensive, it would be a serious burden for the Examiner to search all these groups together. Moreover, concerning species requirement, detection of SEQ ID NO:1 in prostate tissue does not necessarily mean that it would be detected in bodily fluid or in cells, such as cells in tissue culture.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1, 6, the polynucleotide of SEQ ID NO:1, and species tissues are examined in the instant application, wherein claim 1 is examined only to the extent of detection of mRNA level of CSG..

OBJECTION

Claims 1, 6 are objected to because claims 1 and 6 recite a non-elected invention, i.e. a method for diagnosing the presence of prostate cancer, comprising measuring the level of CSG (which reads on the protein level of CSG) in cells, tissues or bodily fluid, wherein said CSG comprises SEQ ID NO:2. Proper amendment of claims 1 and 6 is required.

Claim Rejections - 35 USC § 112, SECOND PARAGRAPH

Claims 1, 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1, 6 are indefinite for the use of the designation of "CSG" in claim 1 as the sole means of identifying the claimed polynucleotide. The use of laboratory designation only to identify a particular polynucleotide renders the claim indefinite because different laboratories may use the same laboratory designations to define completely distinct polynucleotides. Amendment of the claims to include physical and/or functional characteristics of "CSG" which unambiguously define "CSG" is required.

2. Claims 1, 6 are indefinite for the use of the language "change" in the levels of CSG in claim 1. It is not clear whether it is intended to refer to an increase or a decrease in the level of CSG.

3. Claims 1, 6 are indefinite for the use of the language "normal" in claim 1. It is not clear what is normal and what is not normal.

4. Claims 1, 6 are indefinite for the use of the language "associated" in claim 1. It is not clear what type of association is referred to.

Claim Rejections - 35 USC § 112, FIRST PARAGRAPH, SCOPE

1. Claims 1, 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence of prostate cancer, comprising measuring the mRNA level of the CSG polynucleotide of SEQ ID NO:1 in prostate tissue, wherein a increase in said level as compared to the non-diseased control tissue is an indication with the presence of prostate cancer, does not reasonably provide enablement for a method for diagnosing the presence of prostate cancer, comprising measuring the levels of CSG in tissues, wherein a "change" in said

levels as compared to the normal human control is associated with the presence of prostate cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1, 6 are drawn to a method for diagnosing the presence of prostate cancer, comprising measuring the levels of CSG in tissue, wherein a "change" in said levels as compared to the normal human control is associated with the presence of prostate cancer, wherein the CSG comprises SEQ ID NO:1.

The specification discloses that the mRNA levels of SEQ ID NO:1 is higher in prostate cancer tissues as compared to normal adjacent tissue (table 2 on page 21).

One cannot extrapolate the teaching in the specification to the claims, because a change could be an increase or a decrease, which are opposite of each other. Thus it is not clear how the opposite results on the mRNA levels of SEQ ID NO:1 would indicate the presence of prostate cancer.

In the absence of a teaching of how to detect prostate cancer by detecting an increase or a decrease or both of the mRNA levels of SEQ ID NO:1 in prostate tissues, it would have been undue experimentation for one of skill in the art at the time the invention was made to practice the claimed invention.

2. Claims 1, 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence of prostate cancer, comprising measuring the mRNA level of the CSG polynucleotide of SEQ ID NO:1 in prostate tissue, wherein a increase in said level as compared to the non-

diseased control tissue is an indication with the presence of prostate cancer, does not reasonably provide enablement for a method for diagnosing the presence of prostate cancer, comprising measuring the levels of CSG in " any tissue", wherein a change in said levels as compared to the normal human control is associated with the presence of prostate cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1, 6 are drawn to a method for diagnosing the presence of prostate cancer, comprising measuring the levels of CSG in "tissues", wherein a change in said levels as compared to the normal human control is associated with the presence of prostate cancer, wherein the CSG comprises SEQ ID NO:1.

The specification discloses that the mRNA levels of SEQ ID NO:1 is higher in most cancer tissues of the prostate, bladder, colon, kidney, liver, lung, mammary gland, pancreas, small intestine and testis, as compared to normal adjacent tissue from an individual with prostate cancer (table 2 on page 21).

The claims encompass a method for diagnosing the presence of prostate cancer, comprising measuring the levels of CSG in any cancer tissue besides prostate cancer tissues, wherein a change in said levels as compared to the normal human control is associated with the presence of prostate cancer, wherein the CSG comprises SEQ ID NO:1.

One cannot extrapolate the teaching in the specification to the claims, because it is not clear from the specification, whether cancers from bladder, colon, kidney, liver,

lung, mammary gland, pancreas, small intestine and testis are primary cancers or from metastatic prostate cancer. In either circumstances, however, detection of an increase in levels of mRNA levels of SEQ ID NO:1 is an indication of either cancers of these organs, or metastatic prostate cancer, but not prostate cancer *per se*.

Further, since the claims do not recite specific primers for use in the detection of SEQ ID NO:1, detection of SEQ ID No:1 in a tissue such as colon would cross-react and also detect a known colon cancer antigen, as disclosed by WO200122920-A2, Genbank Sequence Database (Accession AAH34981), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available on 05/04/01. As shown by MPSRCH sequence similarity search, the colon cancer antigen, as disclosed by WO200122920-A2 has 99.8% similarity with almost throughout the entire full length of the claimed SEQ ID NO:1, from nucleotide 158 to nucleotide 1840 (MPSRCH search report, 2002, us-09-807-200-1.rng. pages 18-19).

In view of the above, it would have been undue experimentation for one of skill in the art at the time the invention was made to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 6 are rejected under 35 U.S.C. 102(a) as being anticipated by US 6,177244 B1, as evidenced by US 6,287777.

Claims 1, 6 are drawn to a method for diagnosing the presence of prostate cancer, comprising measuring the levels of CSG in tissues, wherein a change in said levels as compared to the normal human control is associated with the presence of prostate cancer, wherein the CSG comprises SEQ ID NO:1.

US 6,177244 B1 teaches detection overexpresssion of NPG-1 (SEQ ID NO:1) in cancerous portion of the prostate (column 52, lines 46-67, and column 53).

Under MPSRCH sequence similarity search, the sequence taught by US 6,177244 B1 is 96% similar to the claimed SEQ ID NO:1, from nucleotide 850 to nucleotide 1254 (MPSRCH search report, us-09-807-200-1.rni, page 4).

US 6,287777 teaches detection overexpresssion of full length NPG-1 sequence (SEQ ID NO:1) in cancerous portion of the prostate (column 54).

Under MPSRCH sequence similarity search, the sequence taught by US 6,287777 B1 is 98.4% similar to almost throughout the entire full length of the claimed SEQ ID NO:1, from nucleotide 63 to nucleotide 1840 (MPSRCH search report, us-09-807-200-1.rni, pages 1-2)

One would have expected that detection of SEQ ID No:1 taught by US 6,177244 B1 would also detect the claimed SEQ ID NO:1. Thus the method of detecting prostate cancer taught by US 6,177244 B1 seems to be the same as the claimed method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

December 10, 2002